

MAR - 1 2001

K010188



**BD**

Indispensable to  
human health

**Summary of Safety & Effectiveness:**

**1. BD Contact Person:**

Greg Morgan  
Head of Regulatory Compliance  
BD Medical  
BD  
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Franklin Lakes, NJ  
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**2. Device Name:** BD Eclipse™ Hypodermic Needle

**3. Predicate Devices:** BD Hypodermic Needle

**4. Product Description/Function:**

**4.1 Description:** Single-use needle with needle protection system. Needle sizes: 18G-25G

**4.2 Function:** Needles are used for aspiration/injection of fluids. The device contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

**5. Comparison of Modified & Predicate Devices:**

**5.1 Descriptive Comparison to a Legally Marketed Device**

The BD Eclipse™ Hypodermic Needles can be used in the same fashion as standard hypodermic needles. When the BD Eclipse™ Hypodermic Needle is in the "ready-to-use" position it provides the same usable injection needle length as a standard hypodermic needle.

Comparison has been made to the standard hypodermic needles. The product is intended to be used for the same general injection and aspiration of fluids. The sharps injury prevention feature of the needle contains a mechanism that covers the needlepoint after use. In the activated position the BD Eclipse™ Hypodermic Needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe

combination.

5.2 Material Changes: There are no significant changes in the materials used for the BD Eclipse™ Hypodermic Needle

5.3 Manufacturing Process Changes: The manufacturing processes are being modified for the addition of the sharps injury prevention feature.

5.4 Manufacturing Site Changes: No new manufacturing site is being utilized.

5.5 Packaging Component Changes: The package design is being modified to accept the larger size of the sharps injury prevention feature.

## **6. Equivalence:**

The sharps injury prevention feature was compared to the predicate devices using the following criteria: activation forces, deactivation force, disconnection from adapter (pin slip off) and impact resistance. The BD Eclipse™ Hypodermic Needle performed in a similar manner to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR - 1 2001

Mr. Greg Morgan  
Head of Regulatory Compliance  
BD Medical Systems  
1 Becton Drive MC226  
Franklin Lakes, New Jersey 07417

Re: K010188  
Trade Name: BD Eclipse™ Hypodermic Needle  
Regulatory Class: II  
Product Code: FMI  
Dated: January 18, 2001  
Received: January 22, 2001

Dear Mr. Morgan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

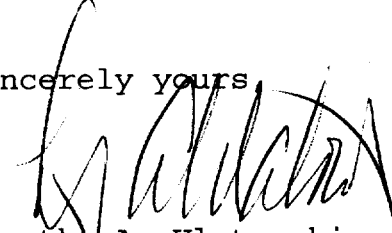
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours

  
Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use:**

The BD Eclipse™ Hypodermic Needle is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse™ Hypodermic Needle is compatible for use with standard luer-slip and luer-lock syringes.

The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needle point after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.



(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

MDN Number 4010188